Coalition of Accredited Laboratories

VIA EMAIL

October 19, 2018

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Subject: October 2, 2018 Hearing on the Environmental Laboratory Accreditation Program

The Coalition of Accredited Laboratories ("CAL") is an organization representing environmental laboratories in the State of California which are accredited by the Environmental Laboratory Accreditation Program ("ELAP"). CAL represents a wide range of laboratories, large and small, publicly and privately owned. We are grateful for the opportunity to submit these comments and look forward to working with the State Water Resources Control Board ("State Board") and ELAP to improve laboratory accreditation. On October 2, 2018, the State Board had an informational item on the agenda about ELAP.

Over the last few years, ELAP has presented an annual update to the Board on its progress in improving the accreditation program. ELAP was transferred to the State Board from the Department of Public Health in 2014. At that time, it had a very poor performance history. The State Board recruited a panel of out-of-state individuals active in laboratory accreditation efforts to participate in an Expert Review Panel ("ERP") to assess the state of ELAP. The ERP, in its report to ELAP and the State Board, identified a number of weaknesses in ELAP and suggested possible solutions to ELAP in late 2015, which developed an implementation plan to put those recommendations into practice in early 2016. The annual report by ELAP to the State Board evolved out of the ERP process.

While most of the reforms that have taken place at ELAP have been universally accepted as needed, one particular proposal has been met with considerable controversy. ELAP has proposed to incorporate by reference into ELAP's regulations a very large portion of the documents produced by The NELAC Institute ("TNI"). Many laboratories, publically and privately owned, both large and small, have expressed grave concerns about the impact that this would have on their operations and the laboratory community overall. TNI, which is mainly about administrative requirements (i.e. paperwork and recordkeeping) and less about laboratory practices, would place large administrative burdens on laboratories without providing any commensurate benefits to the protection of public health or the environment. The fear is

that the additional costs to initiate and maintain TNI's documentation would force many laboratories to drop their accreditation either altogether, or significantly reduce the scope of their accreditation.

At the October 2, 2018 meeting, there were two presentations made that argued in favor of ELAP incorporating the TNI documents into their regulations. One presentation was from Dr. Bruce LaBelle of the Department of Toxic Substance Control and the other Ms. Mitzi Miller of NV5 Dade Moeller, a consulting firm retained by ELAP to conduct On Site Assessments ("OSA"). Both presentations were not made available prior to the hearing so the stakeholders did not get a chance to review, interpret, or formulate a more thoughtful response to the information being presented. Additionally, each made several parallel and complementary arguments. Both speakers, based on the large number of deficiencies identified by NV5 auditors during recent On-Site Assessments ("OSA") , argued that the audit findings can be reduced by the inclusion of TNI requirements into ELAP's regulations. We believe this argument to be incorrect for several reasons, which are listed below:

1) The ERP's recommendation that ELAP adopt the TNI documents was never meant to be a long-term solution and clearly states it to be a short-term solution to the current out of date ELAP regulations.

2) The United States Environmental Protection Agency (USEPA) did not encourage or require the use of TNI in its *"Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, 2008"*.

3) Both Mr. LaBelle and Ms. Miller suggested an improvement in the quality of laboratory data by incorporating TNI requirements into ELAP's regulations. However, the ERP, the USEPA, and even TNI itself have not indicated this. The ERP merely suggested TNI to be a good short-term solution because of the easy and quick implementation; nothing about improving data quality was mentioned or implied.

4) It was argued that an excessive number of deficiencies were found during the recent On-Site Assessments ("OSA") conducted by NV5 and this was why it was important to use TNI requirements. However, taking Ms. Miller's findings at face value, the opposite is clearly the case. These large numbers of deficiencies were found without ELAP using TNI requirements. If ELAP's goal is to minimize deficiencies, TNI adoption is clearly not the solution.

5) It is also not clear that the number of deficiencies found was really as large as Ms. Miller indicated. Although her presentation was quite brief and not very detailed, even among the few details available, many of the "deficiencies" identified are not based on requirements in ELAP's current regulations. In other words laboratories were being evaluated using criteria they are not currently required to comply with under ELAP's current regulations.

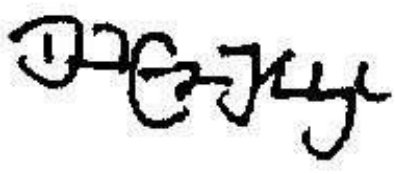
The main point raised was that laboratories accredited by ELAP are doing a very poor job due to the high occurrence of deficiencies and this would be solved by requiring the use of TNI standards. This argument is a rather incongruous one - however, given the fact that ELAP is proposing to reduce the frequency of OSAs in its new regulations. For decades, ELAP has conducted OSAs on a biannual basis. That is how the current regulations are written. In their current draft regulations, ELAP proposes to reduce the frequency

of OSA to once every three years. If ELAP believes that the laboratories it oversees are doing a very poor job, then it would only make sense to increase and not decrease the frequency of OSAs.

Please find an attachment to this letter that discusses the issues raised above in more detail.

We would like to thank the Board for conducting the meeting on October 2, 2018 and giving laboratories and interested parties the opportunity to hear and present information regarding the direction and future of its laboratory accreditation program.

We thank you for your attention.



David Eugene Kimbrough, Ph.D.

Attachment

1) The Expert Review Panel

Dr. LaBelle wrote that to not adopt TNI would: *"Allow some labs to do less than the best practices the Expert Review Panel identified as critical for confidence in the data"*

The ERP did not recommend that ELAP adopt the TNI requirements. The ERP provided ELAP with three options; (1) Create ELAP's own State-specific standard; (2) modify and adopt an existing standard; or (3) adopt an existing standard.

Option 3 is what the ERP recommended without specifying whether it was TNI in particular. Further, their reasoning for recommending Option 3 was: *"The major benefit of adopting an existing standard is that the time and resources needed to implement it will be greatly reduced."* The argument for Option 3 was never to produce higher quality or legally defensible data because high quality and legal defensibility is achieved by following the method as stated.

Later in the report, the ERP suggested TNI documents might be used in the short term: *"The Panel is aware of a number of state, national, and international laboratory standards that could meet the State's needs, but recommends the standard developed by TNI as the most viable one for the State* ***in the short term****. The TNI standard is a standard the State has used in some form previously, albeit not for all laboratories. Adopting a standard that has been implemented as broadly as the TNI standard would allow the State to take advantage of a wealth of available resources and support."* [emphasis added] When the ERP does make a suggestion about TNI, it is only as a short-term fix because of resources and support and not because of 'best practices' or improved data quality.

2) United States Environmental Protection Agency (USEPA)

Dr. LaBelle wrote that to not adopt TNI would mean that: *"California should not follow [US]EPA's recommendation* that drinking water labs have an ISO 17025/ TNI quality system"* according to the Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, 2008. Supplement 1 does not, however actually say that, rather it says:

"Laboratories performing analysis of drinking water under the Safe Drinking Water Act (SDWA) are required to operate a formal Quality Control program. Laboratories should also have a formal Quality Management system documented and in place. Programs that operate in accordance with International Organization for Standardization (ISO) 9001, particularly ISO/IEC 17025 (General Requirements for the Competence of Testing and Calibration Laboratories), are encouraged. ISO/IEC 17025 includes both quality management requirements (based on ISO 9001) and a number of technical requirements specific for testing and calibration laboratories. … The NELAC Institute (TNI) (www.nelac-institute.org), formerly known as the National Environmental Laboratory Accreditation Conference (NELAC), implements an accreditation program with a Quality Management approach

that is based on ISO/IEC 17025; the TNI program has also integrated SWDA-based requirements from the drinking water program into its standards."

a) Supplement 1 appends the Laboratory Certification Manual (LCM). The LCM is not cited in California regulation nor is it Federal Regulation, as the LCM itself explicitly states. Specifically it says: *"This is a guidance manual and not a regulation"*.

b) In fact, in the LCM itself says this and says that State Accreditation programs should NOT use this document for their programs. Specifically it states: *"EPA intends to use this manual for its own use in certifying laboratories for analysis of drinking water contaminants. … States wishing to adapt the procedures and criteria of this manual for their own certification program should revise it to accurately reflect accurately their State certification program."*

c) Supplement 1 does not recommend TNI. It merely notes that TNI is consistent with ISO 17025 and that ISO 17025 is a widely used Quality Management System. The only "requirement" in the Supplement 1 is for there to be a Quality Management System, not that it be either ISO 17025 or TNI. Supplement 1 only has one sentence about TNI: *"The NELAC Institute (TNI) (www.nelac-institute.org), formerly known as the National Environmental Laboratory Accreditation Conference (NELAC), implements an accreditation program with a Quality Management approach that is based on ISO/IEC 17025; the TNI program has also integrated SWDA-based requirements from the drinking water program into its standards."* This is not a requirement or even a recommendation.

d) It is entirely possible, and routinely practiced, to have a Quality Management system without using either ISO 17025 or TNI. California Environmental Protection Agency has been doing this for decades.

3) The NELAC Institute

Although the ERP did not actually recommend TNI as a long-term solution for ELAP's outdated regulations, ELAP proceeded as if it had. In April 2016, ELAP sponsored two all day workshops, one in Rancho Cordova and one in Costa Mesa. They were intended to show how Option 3, using TNI, would work if it were adopted into regulations. Christine Sotelo, the ELAP program manager, opened the workshop by saying that ELAP had not yet decided on which of the three options it would select but they favored TNI because it would be easier to implement and adopt because ELAP would not have to write its own regulations. Jerry Parr, the Executive Director of TNI, then spoke. He said:

"So let us start with the purpose of accreditation. Accreditation does not guarantee quality data, it does not prevent against fraud, it does not prevent laboratories from cheating, it is always equated to a driver's license. You are competent to operate a motor vehicle; it is a demonstration of competence. The laboratory is capable of generating quality results. There is a corollary to that, that if you are a competent laboratory you are more likely to be able to generate data of the appropriate quality."

Mr. Parr is correct. Having a driver's license does not mean that a driver will operate an automobile safely and within the bounds of the law, only that he or she is capable of doing so. The same is true for having a Certificate of Accreditation from ELAP; it means that the laboratory is capable of producing precise and accurate results, not that it will.

4) ELAP's Current Regulations

Dr. LaBelle wrote: *"Deficiencies noted during current lab[oratory] assessments are despite not because of current ELAP reg[ulation]s"*

Dr. LaBelle is certainly correct in this matter. Ms. Miller identified a great many deficiencies, which she quantified and categorized most effectively. If we take Ms. Miller's assessments at face value, she and her employees were able to identify a great many deficiencies using the current regulations, regulations that do not employ any of TNI's requirements. ELAP's regulations have not been updated for over 20 years so with more up-to-date regulations, it might be expected that even more deficiencies might have been found. Suffice it to say, ELAP and NV5 were able to do what they considered a very good job of finding deficiencies without TNI requirements.

5) Deficiencies

Dr. LaBelle wrote: *"If you can't cite it, you can't write it"*, meaning that deficiencies cannot be written if a relevant section of regulation or state cannot be cited. This is most certainly true.

Ms. Miller wrote: *"A 'deficiency' is a failure to comply with regulations or published methods."* If Ms. Miller means published methods cited in ELAP's regulations that is certainly true as well.

If staff conducting OSAs are to write a deficiency, they have to be able to cite either statute (the Environmental Laboratory Accreditation Act - California Health and Safety Code (HSC) 100825 – 100920.5) or regulation (California Code of Regulations Title 22, Chapter 19 § 64801 – 64860). Parts of Chapter 19 incorporate by reference Federal regulations, specifically the Code of Federal Regulations (CFR) Title 40, Section 141 and 136 from July of 1992. A deficiency issued by ELAP, would need to cite one of these three sources. Since NV5 only assessed laboratories accredited for analyzing samples for compliance with Safe Drinking Water Act (SDWA), only 40 CFR 141 would apply.

Unfortunately, Ms. Miller did not provide any specific examples of how laboratories failed to comply with ELAP's regulations in her presentation, which might include citations. However, one might be able to deduce the nature of the deficiencies from the descriptions provided in Ms. Miller's presentation and from laboratories that have shared their Deficiency Letters with their fellow laboratories.

a. Proficiency Testing

Ms. Miller indicated that at least one laboratory was cited for analyzing a Proficiency Testing Sample (PTS) more than once. A condition of accreditation is for laboratories to purchase PTSs from an ELAP approved (sample) provider, analyze them, and report the value obtained for tests and analytes for which the laboratory is seeking renewed or new accreditation. The laboratory does not know the true concentration of the target analytes and must return results within a vendor-determined time and within acceptable ranges. PTSs arrive in specially marked packages and are typically concentrated, which means that the sample must be diluted before they can be analyzed. It is indeed a common practice for laboratories to analyze these samples, upon which their accreditation depends, more than once.

A review of the HSC, Title 22, and 40 CFR 141 found no requirement that prevents a laboratory from analyzing a PTS more than once. However, laboratories that had been assessed by NV5 and were cited for this "deficiency" and shared their deficiency letters showed that the NV5 personnel cited the LCM. As noted above, the LCM is not cited in either state or federal regulations and is itself not a regulation. The LCM *"…is intended to assist [US]EPA in implementing 40 CFR 142.10(b)(4) by specifying criteria and procedures [US]EPA uses in evaluating principal State laboratories for certification."* Primacy states, those that implement the SDWA, must either have a Principal State Laboratory (PSL) or accredit laboratories to do the same work that the PSL would perform. The LCM is only for the USEPA to assess PSLs, not accredited laboratories. As the LCM itself notes: *"This manual is not a rule, is not legally enforceable, and does not confer legal rights or impose legal requirements upon any member of the public, States or any other Federal agency."* The LCM goes on to note: *"States wishing to adapt the procedures and criteria of this manual for their own certification program should revise it to accurately reflect accurately their State certification program."* The USEPA and the LCM could not be clearer, the LCM should not be used by State accreditation programs to assess accredited laboratories.

Quite aside from the fact that there is no legal basis for ELAP or NV5 to cite a deficiency for multiple analyses of PTSs, this is not a correct interpretation of what the LCM actually says. In Section 13 it is stated: "PT samples should be analyzed in the same manner as routine samples." Of course, it is not, in most cases, even physically possible to analyze PTSs exactly like routine samples as they require dilution. Beyond that, the text says "should", not "must". When the LCM uses the word "should", as the LCM itself explicitly states, that this is a recommendation, not a requirement. So even if the LCM were a regulation, it does not require that PTS be treated exactly the same as routine samples and it certainly does not preclude multiple analyses.

NV5, it would appear, has cited laboratories for failing to comply with the LCM as deficiencies. If this is so, it might turn out that there are not quite so many deficiencies as was it made to appear.

b. Gravel Floor

Ms. Miller cites a laboratory that had gravel on the floor of a laboratory where metals were being analyzed. As above, there are no regulations or statutes, which preclude a laboratory from having gravel on the floor. Ms. Miller suggests that this could be source of contamination for the analysis of

metals but does not actually say that this occurred in this laboratory. Indeed, methods used by laboratories for metals in drinking water are required to run "blanks". Containing reagent grade water that are treated like every other sample, blanks are used to determine if contamination is indeed occurring in these samples. If the gravel on the floor were a source of contamination, it would be evident in the blanks and then that would be the basis for a deficiency. However, this does not appear to be the case. The citation appears to be merely for having gravel.

c. Additional notes

Without more specific details, it is not possible to further assess just how accurate Ms. Miller's quantification of deficiencies is. However, when Ms. Miller wrote: *"Method related items are not new to the laboratories"* she is implying that laboratories have known about these requirements for a long time. At least in the above cases that was not true, laboratories in California have never been held to these sorts of requirements before because they are not in statute or regulation. No doubt there are plenty of legitimate deficiencies that were found, no one doubts that laboratories do less than a perfect job and need routine OSAs to keep them working at their best. Indeed, the entire point of laboratory accreditation is for ELAP staff conduct OSAs routinely to help keep laboratories doing their best.